Medacta International

JUN 12 2014

510(k) Summary

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Date Prepared: February 5, 2014

DEVICE INFORMATION

Trade/Proprietary Name: Mecta-C Cervical Plate
Common Name: Anterior Cervical Plate
Classification Name: appliance, fixation, spinal intervertebral body
21 CFR 888.3060
Class II
Product Code(s): KWQ

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K000742	CSLP	Synthes	3/29/2000
K001794	Anterior Cervical Plate	EBI	7/12/2000
K974706	ABC Plate	Aesculap	3/13/1998
K050451	Vectra	Synthes	3/24/2005
K081038	Atlantis	Medtronic	8/15/2008

Product Description

The Mecta-C Cervical Plate consists of single and multilevel plates up to four levels used to stabilize the cervical spine in order to promote fusion. The cervical plates are offered with lengths between 20 and 92mm and are made of Ti6Al4V ELI (ISO 5832-3/ASTM F 136). The plate is fixed on the vertebral body either by means of fixed angle or variable angle screws. Screws are available in 4mm and 4.5mm diameters with a length between 12mm and 22mm. The screws consist of an inner locking screw and the outer main screw shaft and are available with a self-tapping or a self-drilling tip. The main screw shaft is made of Ti6Al4V ELI (ISO 5832-3/ASTM F 136) and the locking screw is made of Ti6Al4V ELI (ISO 5832-3/ASTM F 136). The cervical plates and screws are available both in sterile and unsterile packaging.

Indications for Use

The Mecta-C plate system is intended for anterior Interbody screw/plate fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis,or scoliosis), 5) psuedarthrosis, and/or 6) failed previous fusion. This device system is intended for anterior cervical intervertebral body fusions only.

Comparison to Predicate Devices

The indications for use, design features and materials of the Mecta-C Cervical Plate are substantially equivalent to those of the predicate devices. The substantial equivalence of the Mecta-C Cervical Plate implants are supported by the performance testing, materials information, and data analysis provided within this Premarket Notification.

Performance Testing

The Mecta-C Cervical Plate biomechanical tests are defined according to the Guidance for Industry and FDA Staff – Spinal System 510(k)s, issued on May 3, 2004. The guidance suggests performing static and dynamic compression tests as well as static torsion tests. Tests were performed on a two level construct as suggested in the ASTM F1717 standard. In addition to the recommended tests, screw push-out tests were performed in order to prove the substantial equivalence of the screw plate interface. The biomechanical test results of the Mecta-C Cervical Plate constructs were compared with results of the predicate devices and were determined not to be worst case.
The Mecta-C Cervical Plate was tested using the worst-case device for each of the following tests:
Static Compression yield strength - ASTM F1717

Static Compression Stiffness - ASTM F1717
Dynamic Compression - ASTM F1717
Static Torsion yield torque - ASTM F1717
Static Torsion Stiffness - ASTM F1717
Screw plate interface strength: Push-out

Conclusion:
Based on the above information, the Mecta-C Cervical Plate can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2014

Medacta International SA
% Mr. Adam Gross
Medacta USA
1556 West Caroll Avenue
Chicago, Illinois 60607

Re: K140361
Trade/Device Name: Mecta-C Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 14, 2014
Received: May 15, 2014

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140361

Device Name
Mecta-C Cervical Plate

Indications for Use *(Describe)*
The Mecta-C plate system is intended for anterior Interbody screw/plate fixation from C2 to T1.
The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis,or scoliosis), 5) psuedarthrosis, and/or 6) failed previous fusion. This device system is intended for anterior cervical intervertebral body fusions only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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